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PATENT
Docket No. 564682000100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:	Examiner: Not Yet Assigned
Lutz BIEDERMANN et al.	Group Art Unit: 3732
Serial No.: 10/763,431	
Filing Date: January 22, 2004	
For: BONE SCREW	

REQUEST FOR DECLARATION OF INTERFERENCE UNDER 37 CFR 1.604(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.604(a), applicants respectfully request that an interference be declared between this application and Carbone U.S. Patent Application Serial No. 10/091,068, filed March 5, 2002, published as U.S. Patent Publication No. 2003/0055426 A1 on March 20, 2003 (hereinafter "Carbone"). Applicants brought Carbone to the Examiner's attention in the Second Preliminary Amendment filed March 18, 2004. Carbone is not assigned on its face, but applicants have information that indicates that Carbone's assignee is some member of the Stryker Corporation family of companies. A copy of the Carbone publication is attached for the Examiner's convenience.

In accordance with 37 CFR 1.607(b), this application is now to be examined with special dispatch within the Office.

Applicants have already submitted under separate cover a Revocation of Power of Attorney and Power of Attorney under 37 CFR 3.73 and Change of Address and an Information Disclosure Statement. Applicants attach hereto a copy of the publication of their parent

application, U.S. Patent Application Publication No. 2002/0058942 A1, now U.S. Patent No. 6,736,820, issued May 18, 2004; and sworn translations of applicants' German priority applications. The certified copies of applicants' German priority applications are already of record in the parent application file and need not be resubmitted in this application. Applicants are submitting concurrently herewith a Third Preliminary Amendment to add new claims 40-42.

PROPOSED COUNTS

Proposed Count 1.

The assembly or coupling element of Carbone claims 1-9, 11-13, 15-18, 20, 22-31, 34-37, 41 and 42

or

the assembly or coupling element of applicants' claims 6-35 and 40-42.

Proposed Count 2.

The method of Carbone claims 44-47

or

the method of applicants' claims 36-39.

Applicants are presenting separate device and method counts in view of the restriction requirement entered in Carbone's pending application, without prejudice to moving to substitute a single device count in the interference once it is declared.

The Proposed Counts are presented in this form because of potential issues of patentability with respect to Carbone's broad claims which must be resolved in *ex parte* prosecution or in the interference and to avoid issues of interference in fact prior to declaration of the interference.

CORRESPONDENCE OF CARBONE'S CLAIMS TO COUNTS

In view of the wording of the Proposed Counts above, Carbone's claims 1-9, 11-13, 15-18, 20, 22-31, 34-37, 41, 42 and 44-47 correspond exactly to the Proposed Counts.

Carbone's claims 10, 14, 19, 21, 32, 33, 38-40 and 43 add limitations that do not patentably distinguish the subject matter of these claims as a whole from the other claims making up the Proposed Counts in view of U.S. Patent Nos. 5,672,176 (Biedermann '176), 6,471,705 (Biedermann '705) and 5,476,464 (Howmedica '464, owned by Stryker) and European Patent Application No. EP 0885598 A2 (Howmedica '598, also owned by Stryker) and thus correspond substantially to the Proposed Counts. Copies of these references are attached hereto for the Examiner's reference.

Carbone claims 10 and 32 are unpatentable over the subject matter of the Proposed Counts in view of Howmedica '598 and Biedermann '176. Howmedica '598 Fig. 12 discloses a coupling element 108 including a seat 114 that is substantially conical with sidewalls tapering inwardly toward the lower end of the coupling element. In addition, Biedermann '176 Figs. 1-3 disclose a coupling element 5 including a seat 16 that is substantially conical with sidewalls tapering inwardly toward the lower end of the coupling element, as illustrated in FIGS. 1-3 of the reference.

Carbone claim 14 is unpatentable over the subject matter of the Proposed counts in view of Howmedica '598, which shows an anchoring element, bone screw 100, having a neck adjacent the head that includes a concave surface, as illustrated in Figs. 10 and 11 of the reference.

Carbone claim 19 is unpatentable over the subject matter of the Proposed Counts in view of the bone hooks 10 shown in Howmedica '464. Howmedica '464, which is prior art under 35 USC 102(b), shows that using the claimed hooks and barbs was well known in the prior art and would have been obvious in light of the subject matter of the Proposed Counts and the claims corresponding exactly thereto.

The "chamfer" at the upper opening of the coupling element of Carbone claims 21 and 33 would have been obvious to persons skilled in the art because forming such chamfers to provide relief or ease of insertion or removal is well-known in structures of the kind claimed.

Carbone claims 38-40 are unpatentable over the subject matter of the Proposed Counts because the angles of intersection set forth in claims 38-40 would have been obvious for use in the assembly of the Proposed Counts because of the degrees of movement desired.

Carbone claim 43 is unpatentable over the subject matter of the Proposed Counts because it would have been obvious to provide a second bore extending from the second plane of the coupling assembly toward the upper end of the coupling element in view of Fig. 1 of Biedermann '705, which shows a second bore in a coupling element. Since this second bore in the second plane would have to have a second longitudinal axis, the angle of intersection of which as set forth in claim 43 would have been obvious based on the angle of intersection of the first and second planes of claim 42.

APPLICANTS' CLAIMS CORRESPONDING TO THE COUNTS

In view of the wording of the Proposed Counts, applicants' claims 6-42 correspond exactly to the Proposed Counts.

SUPPORT FOR CLAIMS IN APPLICANTS' DISCLOSURE

Applicants are adding claims 40-42 concurrently herewith and provide the following chart applying them (and their base claims as shown in italics) to the disclosure of this application.

Applicants' Claims	Supporting Disclosure in Involved Application (As Shown in Published Parent Application No. 2003/0058942 A1))
6. A bone fixation assembly comprising:	The overall assembly as shown in FIGS. 1-4, which is the combination of screw member 1 and receiving part 5.
a coupling element having a first bore coaxial with a first longitudinal axis and a second bore, coaxial with a second longitudinal axis, wherein said first and second longitudinal axes are transverse to one another;	The receiving part 5 corresponds to the coupling element. The first bore 6, as disclosed in FIGS. 1-4 and mentioned in paragraph [0014], has a longitudinal axis of symmetry 15, as generally disclosed in paragraphs [0014] and [0017]. The second bore 7 is formed in the receiving part 5 and has its own axis of symmetry, as shown in FIGS. 1-4 and explained in paragraphs [0014] and [0017]. The transverse configuration of the axes of symmetry of the first and second bores is explained in detail in paragraph [0017].
and an anchoring element assembled with said coupling element , said anchoring element having a first end for insertion into bone.	The anchoring element corresponds to screw member 1, the threaded section 2 of which is designed as the end of the screw member that is to be inserted into the bone.
7. The assembly of Claim 6 wherein said coupling element has an upper end and a lower end ,	FIG. 3 shows receiving part 5 with an upper end (approximately adjacent reference numeral 14 in the figure) and a lower end (approximately adjacent reference numeral 11 in the figure).
said first bore extending from said upper end toward said lower end and said second bore extending from said lower end toward said upper end.	The first bore 6 starts from the upper end of the receiving part 5 in the direction of the lower end, and the second bore 7 starts from opening plane 11 and extends in the direction of the upper end of the receiving part 5.
12. The assembly of Claim 7, wherein said second bore includes a seat adjacent said lower end of said coupling element,	As explained in paragraph [0014], the bottom of first bore, which perforce is at the top of the second bore, is constructed as a spherically shaped region facing toward the bottom of the receiving part. As explained in paragraphs [0015] and [0018], the embodiments of FIGS. 1 and 3 both have a circular countersink or chamfer 10 made in the edge between the opening plane 11 of the

	second bore 7 and the edge 12 of the first bore 6 so as to leave a small peripheral section which belongs to the spherical seat.
and wherein said seat is adapted to engage said anchoring element.	Paragraph [0014] explains that the spherical seat has a radius substantially equal to the radius of the spherically shaped head 3 of the anchoring element.
13. The assembly of Claim 12, wherein said anchoring element has a head having a substantially spherical underside adapted to engage said seat.	Paragraph [0014] explains that the spherical seat has a radius substantially equal to the radius of the spherically shaped head 3 of the anchoring element.
28. A coupling element having an upper end and a lower end comprising:	FIG. 3 shows receiving part 5 with an upper end (approximately adjacent reference numeral 14 in the figure) and a lower end (approximately adjacent reference numeral 11 in the figure).
a first section extending from said upper end toward said lower end of said coupling element, said first section including a first bore coaxial with a first longitudinal axis;	The receiving part includes a first bore 6 that starts from the upper end of the receiving part 5 and extends in the direction of the lower end of the receiving part. This is the "first section." FIGS. 1 and 3 show that this first bore has a longitudinal axis. See also, paragraph [0017].
a second section extending from said lower end toward said upper end of said coupling element, said second section having a second bore coaxial with a second longitudinal axis that intersects said first longitudinal axis; and	The receiving part also includes a second bore 7 that starts from opening plane 11 and extends in the direction of the upper end of the receiving part 5. This is the "second section." FIGS. 1 and 3 show that this second bore has a longitudinal axis. See also, paragraph [0017]. As explained in paragraphs [0015]-[0019], especially in paragraph [0017], the longitudinal axes of the first and second bores intersect.
rod-receiving openings extending between said upper and lower ends of said coupling element and being adapted to receive an orthopedic rod.	The rod receiving openings are the U-shaped recesses 8 in the receiving part 5 having side legs 13 and 14 which extend toward the open end of the receiving part. See, paragraph [0014].
29. The coupling element of Claim 28, wherein said second bore includes a seat adjacent said lower end of said coupling element.	As explained in paragraph [0014], the bottom of first bore, which perforce is at the top of the second bore, is constructed as a spherically shaped region facing toward the

	bottom of the receiving part. As explained in paragraphs [0015] and [0018], the embodiments of FIGS. 1 and 3 both have a circular countersink or chamfer 10 made in the edge between the opening plane 11 of the second bore 7 and the edge 12 of the first bore 6 so as to leave a small peripheral section which belongs to the spherical seat.
30. The coupling element of Claim 29, wherein said seat is adapted to engage a head of an anchoring element secured with said coupling element so that said coupling element and said anchoring element are pivotable relative to one another.	Paragraph [0014] explains that the spherical seat has a radius substantially equal to the radius of the spherically shaped head 3 of the anchoring element. Paragraph [0017] explains how the screw member is pivotable relative to the receiving part, as is apparent from FIG. 3
33. A coupling element for a bone fixation assembly comprising:	The overall assembly as shown in FIGS. 1-4, which is the combination of screw member 1 and receiving part 5.
an upper end defining a first plane; *a lower end defining a second plane;*	FIG. 3 shows receiving part 5 with an upper end (approximately adjacent reference numeral 14 in the figure) and a lower end (approximately adjacent reference numeral 11 in the figure).
at least one bore extending between said upper end and said lower end, said at least one bore being adapted to receive an anchoring element,	The first bore 6 starts from the upper end of the receiving part 5 in the direction of the lower end, and the second bore 7 starts from opening plane 11 and extends in the direction of the upper end of the receiving part 5.
wherein said first plane and said second plane intersect one another.	As explained in paragraphs [0015]-[0019], especially in paragraph [0017], the planes of the longitudinal axes of the first and second bores intersect.
34. The coupling element as claimed in Claim 33, wherein said coupling element has a first bore extending from said upper end toward said lower end and a second bore extending from said lower end toward said upper end,	The first bore 6 starts from the upper end of the receiving part 5 in the direction of the lower end, and the second bore 7 starts from opening plane 11 and extends in the direction of the upper end of the receiving part 5.
and wherein said first and second bores are angled relative to one another.	Disclosed in paragraph [0017].

40. The assembly of claim 13, wherein said anchoring element includes a neck adjacent said head having a diameter less than the diameter of said threaded portion for facilitating pivotal movement of said coupling element and said anchoring element relative to one another.	As can be seen from FIGS. 1 and 3, the screw member has a unthreaded portion on its shank between the head 3 and threaded section 2 that is smaller in diameter than the outer diameters of the threads.
41. The coupling element of Claim 30, wherein said inner surface includes threads adjacent said upper end thereof for engaging a locking element for securing an orthopedic rod within said rod receiving openings of said coupling element.	As explained in paragraph [0014], a thread for engagement with a nut or screw is provided at the free ends of the side legs 13, 14 that serves to fix a rod inserted into the U-shaped recess 8.
42. The coupling element of Claim 34, wherein said locking element has external threads adapted for threading into said internal threads of said coupling element.	The locking element disclosed in paragraph [0014] is threaded to engage with the threads at the free ends of side legs 13, 14.

COMPLIANCE WITH 35 USC 135(b)

Carbone was published March 20, 2003, less than one year prior the presentation in this application of claims 6-39 in the Second Preliminary Amendment filed March 18, 2004. The chart on pages 7 and 8 of the Second Preliminary Amendment explains the correspondence between claims 6-39 and Carbone's claims. Thus, claims presented in this application within the time period specified by 35 USC 135(b) interfered with Carbone's claims under the criteria approved by the court in *In re Berger*, 279 F.3d 975, 61 USPQ2d 1523 (Fed. Cir. 2002). Thus, applicants are in full compliance with 35 USC 135(b).

APPLICANTS' ENTITLEMENT TO BENEFIT

This application is a continuation of U.S. Application Serial No. 10/037,698, filed November 9, 2001, now U.S. Patent No. 6,736,820, which claims priority from German patent application Nos. 100 55 888.7, filed November 10, 2000, and 100 65 397.9, filed December 27, 2000. Certified copies of these applications are of record in the prosecution file of the parent application and are being resubmitted in this application so that the record of this application on

priority will stand complete by itself. The sworn translations of these priority documents attached hereto demonstrate applicants' entitlement to the benefit of an effective filing date of November 10, 2000, upon declaration of an interference.

The following claim chart demonstrates that applicants' first German priority application discloses at least a species within the scope of the Proposed Counts, showing applicants' entitlement to the benefit of the November 10, 2000, filing date of that application:

Proposed Counts	Support in Translation of DE 100 55 888.7
Proposed Count 1 (Applicants' Claim 6.) A bone fixation assembly comprising:	The overall assembly as shown in FIGS. 1-4, which is the combination of screw member 1 and receiving part 5.
a coupling element having a first bore coaxial with a first longitudinal axis and a second bore, coaxial with a second longitudinal axis, wherein said first and second longitudinal axes are transverse to one another; and	The receiving part 5 corresponds to the coupling element. The first bore 6, as disclosed in FIGS. 1-4 and mentioned at page 3, lines 2-3, has a longitudinal axis of symmetry 15, as generally disclosed at page 3, lines 25-26 and 31, and at page 4, lines 8-9. The second bore 7 is formed in the receiving part 5 and has its own axis of symmetry, as shown in FIGS. 1-4 and explained at page 3, lines 3-5, and page 4, lines 4-9. The transverse configuration of the axes of symmetry of the first and second bores is explained in detail at page 4, lines 3-14.
an anchoring element assembled with said coupling element, said anchoring element having a first end for insertion into bone.	The anchoring element corresponds to screw member 1, the threaded section 2 of which is designed as the end of the screw member that is to be inserted into the bone.
Proposed Count 2. (Applicants' Claim 36) A method of stabilizing an area of the spine of a patient comprising:	The overall assembly as shown in FIGS. 1-4, which is the combination of screw member 1 and receiving part 5.
providing a coupling element having first and second sections that are angled relative to one another, said coupling element having rod-receiving openings for securing an orthopedic rod;	The receiving part 5 corresponds to the coupling element. The receiving part 5 has first bore (or section) 6, as disclosed in FIGS. 1-4 and mentioned at page 3, lines 2-3, which has a longitudinal axis of symmetry 15, as generally disclosed at

	page 3, lines 25-26 and 31, and at page 4, lines 8-9. The second bore (or section) 7 is formed in the receiving part 5 and has its own axis of symmetry, as shown in FIGS. 1-4 and explained at page 3, lines 3-5, and page 4, lines 4-9. The transverse configuration of the axes of symmetry of the first and second bores, which results in first and second sections that are angled relative to each other, is explained in detail at page 4, lines 3-14. The receiving part 5 has a U-shaped recess 8 (shown in FIGS. 1, 3 and 4) into which a rod may be inserted, as explained at page 3, lines 13-22.
assembling said coupling element with an anchoring element;	The anchoring element corresponds to screw member 1, the threaded section 2 of which is designed as the end of the screw member that is to be inserted into the bone. As explained at page 2, line 21, to page 3, line 22, the screw member and receiving part are assembled for use.
after the assembling step, securing said anchoring element in bone;	The German priority application at page 1, line 11, to page 2, line 10, discloses the invention as constituting specific improvements on the bone screw disclosed in U.S. Patent No. 5,672,176 (Biedermann '176, attached hereto). Biedermann '176 discloses assembling the screw member and the seat part, corresponding to the anchoring element and receiving part claimed in this application, respectively, before screwing the screw member into the bone. Col. 3, lines 23-46. The German priority application also states at page 3, lines 5-10, that the screw member is guided into the first bore and that the head of the screw goes down to the bottom of the first bore. Furthermore, it is apparent from all of the art of record that bone screws of this type are assembled prior to screwing the anchoring element into the bone. Persons skilled in the art would thus recognize immediately from the disclosure of the

	German priority application that the anchoring element is screwed into a bone after being assembled with the receiving part.
moving said coupling element relative to said anchoring element to align said rod-receiving openings with said orthopedic rod;	As noted, this invention is used in an improved version of the method disclosed in Biedermann '176, which includes this step as disclosed at col. 3, lines 44-55. At page 1, lines 19-27, the German priority application also describes the method as allowing the head to be pivotable so that even after the anchoring element is secured to a vertebral segment, it is possible to orient the receiving part receiving the rod.
securing said orthopedic rod in said rod-receiving openings; and after the securing step, locking said coupling element from further movement relative to said anchoring element.	At pages 3, lines 13-22, the German priority application explains that a nut or screw inserted into a thread at the free ends of the U-shaped recess 8 serves to fix a rod inserted into the U-shaped recess.

Since this application has an effective filing date for priority purposes of November 10, 2000, earlier than Carbone's provisional application filing date of September 14, 2001; applicants should be named senior party in the Notice declaring the interference.

CONCLUSION

Applicants have copied claims from Carbone's application into their application. Applicants are presumptively the prior inventors of the claimed subject matter as against Carbone by virtue of their earlier effective filing date and desire an interference to get the PTO's judgment that they are the actual prior inventors entitled to a patent on these claims and that Carbone's claims should be rejected. Applicants' opportunity to do so should not be delayed, as this application is now special pursuant to 37 CFR 1.607(b).

If any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone at (703) 760-7743.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952, referencing Docket No. 564682000100**.

Respectfully submitted,

Dated: July 9, 2004 By: _____

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INDEX

1. U.S. Publication No. 2003/0055426A1
2. U.S. Patent No. 6,736,820
3. U.S. Patent No. 5,672,176
4. U.S. Patent No. 6,471,705
5. U.S. Patent No. 5,476,464
6. EP 0 885 598 A2
7. Sworn English translation of DE Application No. 100 55 888.7
8. Sworn English translation of DE Application No. 100 65 397.9